

# **A Process-centered Tool for Evaluating Patient Safety Performance and Guiding Strategic Improvement**

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## **Abstract**

This paper presents a patient safety applicator tool for implementing and assessing patient safety systems in health care institutions. The applicator tool consists of critical processes and performance measures identified in the context of the 2003 Malcolm Baldrige National Quality Award (MBNQA) Health Care Criteria for Performance Excellence. The Delphi technique was used for gaining consensus from a group of experts and forecasting significant issues in the field of the Delphi panel's expertise. Data collection included a series of questionnaires where the first-round questionnaire was based on literature review and the MBNQA criteria for excellence in health care. Data were tested by an instrument review panel of experts. Twenty-three experts (MBNQA health care reviewers and senior health care administrators from quality award winning institutions) representing 18 States participated in the survey rounds. The study addressed three research questions:

1. What critical processes should be included in health care patient safety systems?
2. What performance measures can serve as indicators of quality for the processes critical for ensuring patient safety?
3. What processes will be critical for patient safety in the future?

This study is significant because the results are expected to assist health care institutions seeking to develop high quality patient safety programs, processes, and services. The identified critical processes and performance measures, which extend the Malcolm Baldrige established framework into the area of patient safety and which are presented as a three-level applicator tool, can serve as a means of evaluating existing patient safety initiatives and of guiding the strategic planning of new safety processes. The patient safety applicator tool utilizes a systems approach and will support health care senior administrators in achieving and sustaining improvement results. It also will assist health care institutions in using the MBNQA Health Care Criteria for Performance Excellence for self-assessment and quality improvement.

## **Introduction**

Strong U.S. Government leadership is essential to support the coordination and institutionalization of health care quality priorities and in implementation of

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clinical performance measures. The Government has been asked to provide guidance on development of standards of care and patient safety accountability throughout the health care system in order to assist in the establishment of the following: performance-based payment policies; removal of major financial barriers to quality improvement; and investment in quality and safety infrastructure, research, and training.<sup>1</sup> Although patient safety approaches have been targeted by recent research and requirements of accrediting organizations, deciding which approach is best remains controversial. Current patient safety regulations have been implemented mainly in response to the number of observed patient safety issues reported in professional publications. If a problem has not been recorded or reported, which is often the case with patient safety-related issues, it is most likely not reflected in patient safety requirements. No systemwide approach or model has been agreed upon thus far. Consensus building methods that use *experts* as a source of knowledge and information, coupled with a comprehensive literature review, are reliable approaches in patient safety research, a field in particular need of rigorous qualitative and consumer-oriented research to fill an existing methodological gap.<sup>2</sup> The output from consensus approaches, such as Delphi, is not an end in itself; rather, dissemination and implementation of the study findings are the ultimate aims of consensus activities and are intended to guide health policy decisionmaking, clinical practice, and research.<sup>3</sup> This study is based on the Malcolm Baldrige National Quality Award (MBNQA) model that has been refined over the last 17 years and adopted in a number of health care institutions for improvement of overall organizational and clinical outcomes. This study strives to expand in theoretically meaningful and practically applicable ways the existing knowledge in the area of patient safety. It provides a three-level applicator tool intended to assist health care leadership in organizations that are at different stages of their patient safety and quality improvement journey.

## Methodology

### Malcolm Baldrige quality framework

The methodological model for this study was the MBNQA framework for performance excellence in health care. The MBNQA was established in 1987 to address the importance of quality as the most significant factor for the trade balance of the United States and is the most prestigious national quality award in the United States. The award is performance oriented and is clearly focused on the importance of integration of quality in institutional business planning.<sup>4</sup> Judges and examiners for the MBNQA are selected on the basis of their experience, quality expertise, and peer recognition. Presidential involvement in the award process (the award is presented by the President of the United States or the Secretary of Commerce) ensures national impact, visibility and prestige for the award winners, wide peer recognition for winners' achievements, and deployment of the winners' results throughout industries in the Nation.<sup>5</sup> The health care criteria for performance excellence were introduced in January 1998. The MBNQA

framework consists of 11 core values and concepts, embodied in seven categories: (1) leadership; (2) strategic planning; (3) focus on patients, other customers, and markets; (4) measurement, analysis, and knowledge management; (5) staff focus; (6) process management; and (7) organizational performance results.<sup>6</sup>

Thus far, there have been four award winners in the category of health care: SSM Health Care (2002), Saint Luke's Hospital of Kansas City (2003), Baptist Hospital, Inc. (2003), and Robert Wood Johnson University Hospital Hamilton (2004). All award winners collect data, allowing for tracking of overall performance and identification of opportunities for improvement within the respective institution. They have made an effort to align institutional operations from top to bottom utilizing a variety of performance improvement approaches.

## **Delphi methodology**

In this study, the Delphi method was used to reach consensus among health care quality improvement and patient safety experts. The Delphi method, a useful way of identifying and measuring uncertainty, has been widely utilized in medical and health services research to define professional roles and to clarify issues in health service organizations. It also has been used to aid in the design of educational programs, make long-term projections of need for care for particular population groups, develop criteria for appropriateness of interventions and clinical protocols, and define adverse effects of reducing medical staffing levels.<sup>3, 7-14</sup> The Delphi method gives panel members an avenue for asynchronous interaction, where they choose to participate in the group communication process at their convenience and relate to questions they feel best qualified to discuss. The Delphi method is a collaborative expert system<sup>7</sup> where the experts are provided with a Delphi design and where they dynamically and actively contribute their knowledge to the system. This method significantly broadens knowledge and effective decisionmaking in health and social care.<sup>15</sup> The selection of criteria that would qualify an individual to participate on a Delphi panel depends on the aims and context of the particular study.<sup>7, 16</sup>

Study data collection included a series of questionnaires. The first-round questionnaire was based on a literature review and the MBNQA criteria for excellence in health care. Subsequently, 23 health care quality improvement experts (MBNQA health care reviewers and senior health care administrators from quality award winning institutions) representing 18 States participated in the survey rounds (Table 1).

The study addressed three research questions:

1. What critical processes should be included in health care patient safety systems?
2. What performance measures can serve as indicators of quality for the processes critical for ensuring patient safety?
3. What processes are critical for patient safety in the future?

**Table 1. Delphi expert panel participants**

<b>Participant characteristics</b>	<b>Number of participants (N = 23)</b>
Examiners for the MBNQA (including ranks of examiner, senior, and judge)	14
M.D. and/or Ph.D.	6
Registered nurse or nurse practitioner	7
Representative of an institution that has applied for or won the MBNQA in the health care category	6
Representative of a health care institution that has won a State quality award	6
Senior hospital administrator	20
Leader in a national organization for health care quality and patient safety	1
Leader in a State organization for health care quality and patient safety	1
Female	17
Male	6

The study had two major phases: (1) creation of the original survey instrument and initial establishment of its content validity by a review panel of three quality improvement and patient safety experts, and (2) conducting three iterations of the survey with the health care quality improvement experts on the Delphi panel.

The original survey instrument consisted of 31 critical processes and 58 performance measures structured along the framework of the MBNQA Health Care Criteria for Performance Excellence. Each performance measure was linked to a critical process, and each critical process had one or more associated performance measures. The critical processes and performance measures included in the initial instrument were identified through an extensive literature review of professional publications on patient safety and health care quality improvement. During the first survey iteration, the Delphi experts assessed the importance of patient safety critical processes and performance measures included in the survey instrument. The Delphi experts were asked to rank the critical processes and performance measures on a Likert-type scale indicating a degree of importance from “very important” (rank of 4) to “unimportant” (rank of 1). Panelists were also asked to add any critical process or performance measure they believed should be included in the questionnaire and were given the opportunity to edit all processes and measures as they deemed appropriate.

The second-round questionnaire included all critical processes and performance measures in the original survey instrument along with additional critical processes and performance measures suggested by panelists in the first round. Three critical processes and six performance measures were corrected, and eight new critical processes and 12 performance measures were added. For each critical process and performance measure, the group rank mean from the first round was included, along with the individual participant rank for each variable. Each expert was then asked to review the group scores and re-evaluate their individual original responses. Changes of ranks were permitted in the process of building consensus.

All critical processes and performance measures for which consensus was not reached during the second survey round were included in the third survey iteration. All critical processes and performance measures suggested by the study participants during the first survey iteration were also included in the third questionnaire. At the conclusion of the third survey round, consensus was reached about the current and future importance of patient safety critical processes and performance measures. At the end of the study, individual experts were asked to give permission for their names to be cited as contributors to this study.

## **Results**

**Question 1:** What critical processes should be included in health care patient safety systems? All identified patient safety critical processes were perceived to be at least “important” to patient safety systems in health care institutions. The Delphi panel perceived the following as milestones for implementation of patient safety systems in health care institutions:

- Health care senior leadership direction.
- Institutional governance.
- Setting of institutional goals for performance review.
- Ensuring that health care information technology is reliable, secure, and user-friendly.

**Question 2:** What performance measures can serve as indicators of quality for the processes critical for ensuring patient safety? All performance measures were considered either “very important” or “important” for implementation of patient safety systems in health care institutions. Thirty-one of the performance measures in the patient safety applicator tool received a rank of “very important” to patient safety systems in the present. These 31 “very important” performance measures were distributed throughout the framework categories with the exception of category 3. As reflected by the group rank means for performance measures in category 7, performance measures based on accreditation standards are considered important for implementation of patient safety systems in health care institutions.

**Question 3:** What processes are critical for patient safety in the future? The Delphi experts forecasted that all critical processes identified in the patient safety applicator tool will have higher importance in the future than in the present. All patient safety critical processes had an increased consensus group rank mean for their future importance in comparison with the group rank mean for their current importance. Three of the patient safety critical processes received a perfect score of 4.0 regarding their future importance to implementation of patient safety systems in the future. These processes were:

- Critical process 1.1.1—How senior leaders communicate the priority of patient safety to all stakeholders.

- Critical process 4.1.2—How the institution collects, tracks, and analyzes patient safety data.
- Critical process 4.2.1—How the institution ensures that its clinical information technology is reliable, secure, and user-friendly.

These processes are considered essential for patient safety systems in health care institutions.

The Delphi panel forecasted that patient safety strategy development and deployment would be critical for the process of implementation of patient safety systems in the future. While customer relationship building was also perceived to be an important area to address, obtaining information and feedback from patients on patient safety issues in order to improve health care delivery was given a higher priority. The Delphi panel reached consensus that the way health care institutions design and determine process requirements for their patient safety systems, along with departmental patient safety infrastructure and interdepartmental coordination of patient safety activities, would be crucial for introducing and improving patient safety. Two performance measures received a perfect score of 4.0. These two performance measures related to ensuring a nonpunitive approach for reporting all adverse events and near misses, and ensuring that an accessible, confidential, and adequately functioning reporting system is in place for reporting all adverse events and near misses.

## **Inclusion criteria for final tool**

This study created a patient safety applicator tool for an institution-wide systems approach to introducing, maintaining, and improving health care patient safety systems. The tool is divided into three levels: beginner, intermediate, and advanced. The criteria for inclusion of critical processes and performance measures in the tool were based on the group mean rank and the standard deviation of the importance of the items in the Delphi surveys. Critical processes and performance measures considered “important” (with a consensus group mean between 2.5 and 3.4) or “very important” (with a consensus group mean equal to or higher than 3.5) for patient safety systems in health care institutions were included in the final patient safety applicator tool. Additionally, each Malcolm Baldrige category was presented with its respective items, areas to address, critical processes, and performance measures. Only critical processes and performance measures identified as most important (highest ranking) per each category item are included at the beginner level (Table 2).

The intermediate level includes processes and performance measures at the beginner level plus essential processes (i.e., identified as “very important”) for the systems approach for patient safety systems management at the organizational level. The advanced level includes the full patient safety applicator tool as identified by the study experts. The three levels of applicator tool are available via the Internet (<http://rchitexas.org/presentations/akins>) or from the corresponding author.

Table 2. Patient safety applicator tool: beginners

Item	Area to address: Critical Process	Performance Measure
<b>Category 1: Leadership</b>		
<b>1.1. Institutional Leadership</b>	<u>Senior Leadership Direction:</u> How senior leaders communicate the priority of patient safety to all stakeholders.	Functioning institutional systems for communicating patient safety policies, issues, and activities to all stakeholders; actively seeking feedback and use of the information for improvement and creating a culture of safety.
<b>1.2. Social Responsibility</b>	<u>Ethical Behavior:</u> How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems.
<b>Category 2: Strategic Planning</b>		
<b>2.1. Strategy Development</b>	<u>Strategic Objectives:</u> How patient safety practices are identified and translated to institution's goals.	Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans, and patient care practices.
<b>2.2. Strategy Deployment</b>	<u>Action Plan Development and Deployment:</u> How the institution develops, monitors, and improves action plans to ensure patient safety.	Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.
<b>Category 3: Focus on Patients, Other Customers, and Markets</b>		
<b>3.1. Patient, Other Customer, and Healthcare Market Knowledge</b>	<u>Patient Safety Market Knowledge:</u> How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	Planned, coordinated, and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies, and practices.
<b>3.2. Patient and Other Customer Relationships and Satisfaction</b>	<u>Satisfaction Determination:</u> How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.
<b>Category 4: Measurement, Analysis, and Knowledge Management</b>		
<b>4.1. Measurement and Analysis of Institutional Performance</b>	<u>Performance Measurement:</u> How the institution collects, tracks, and analyzes patient safety data.	Nonpunitive reporting systems are in place for recording, monitoring, tracking, and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans.
<b>4.2. Information and Knowledge Management</b>	<u>Data and Information Availability:</u> How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc.) is reliable, secure, and user-friendly.	A planned, aligned, and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.



**Table 2. Patient safety applicator tool: beginners, cont.**

Item	Area to address: Critical Process	Performance Measure
<b>Category 5: Staff Focus</b>		
<b>5.1. Work Systems</b>	<u>Staff Performance Management System</u> : How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.	Best patient safety practices and clinical guidelines are adopted and monitored, and clinician performance is evaluated for consistency with these adopted standards.
<b>5.2. Staff Learning and Motivation</b>	<u>Staff Education, Training, and Development</u> : How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments, and different categories of professional caregivers.
<b>5.3. Staff Well-being and Satisfaction</b>	<u>Work Environment</u> : How the institution maintains conducive environment in regard to patient safety.	Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved, and progress towards them is continuously monitored and evaluated.
<b>Category 6: Process Management</b>		
<b>6.1. Patient Safety System</b>	<u>Patient Safety System</u> : How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.	An institutional mechanism exists for continuous monitoring, improvement, and sustainability of patient safety outcomes in healthcare delivery.
<b>6.2. Support Processes</b>	<u>Patient Safety Support Processes</u> : How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	Systems for departmental and interdepartmental communications, collaborations, and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication, and continuous case management are assessed and improved on an ongoing basis.
<b>Category 7: Institutional Performance</b>		
<b>7.1. Patient Safety Institutional Performance</b>	<u>Patient Safety Results</u> : How the institution ensures patient safety.	The institution monitors the administration of high-alert medications.

## Summary of findings

This study identified a systems-based patient safety applicator tool useful for assessing patient safety systems in health care institutions. The advanced level of the tool has 39 critical processes and 60 performance measures. The Delphi panel consensus showed that, at present, leadership involvement and direction is the major factor for building, maintaining, and improving patient safety systems. The Delphi panel also forecasted that patient safety measurement, analysis, and knowledge management will be the leading factors in improving patient safety

systems in the future. In addition, the study results supported the findings identified in the literature review that more aggressive use of quality measurement, data analysis, and knowledge management is needed in health care settings.

The Delphi panel reached consensus that:

- Utilization of national patient safety benchmarks and clinical protocols is an important aspect of patient safety.
- Standardization of health care devices, treatment approaches, and services is necessary in achieving patient safety.
- Technology will be one of the leading change agents for improving patient safety in health care institutions. Patient safety approaches, such as utilization of a computerized physician's order entry, patient barcodes, computerized pharmacology dispensing systems, and reliable infusion pumps and alarm systems, have potential for decreasing medical errors and making health care safer.
- Patient safety education of health care leadership, clinical staff, and patients is critical for improving patient safety.

At present, the prioritization of the patient safety applicator tool categories based on the consensus group rank mean of all processes within each category is as follows:

1. Category 1, Leadership.
2. Category 4, Measurement, analysis, and knowledge management.
3. Category 2, Strategic planning, and Category 6, Process management.
4. Category 5, Staff focus.
5. Category 3, Focus on patients, other customers, and markets.

This hierarchy identified by the experts within the interrelated MBNQA categories shows that at present the commitment to patient safety by institution's leadership is undoubtedly the moving force for institution-wide adoption of patient safety systems. Patient safety outcomes measurement, at the institutional and provider levels, has gained popularity and recognition with recently mandated patient safety outcome requirements. This hierarchy illustrates that the way to start a systemwide patient safety improvement is to ensure leadership knowledge, understanding, and commitment to patient safety.

The importance of the patient safety applicator tool categories in the future, as forecasted by the Delphi experts, is as follows:

1. Category 4, Measurement, analysis, and knowledge management.
2. Category 1, Leadership; and Category 2, Strategic planning.
3. Category 5, Staff focus.
4. Category 6, Process management.

5. Category 3, Focus on patients, other customers, and markets.

The experts' forecast for the future recognizes the growing importance of and emphasis on patient safety outcome data as the driving force for further establishment and strengthening of the business case for patient safety. Measurement and analysis of patient safety outcome data, along with management of patient safety knowledge, will support institutional leadership in choosing the direction for the next patient safety steps in individual health care organizations.

The low priority given to Category 3 (Focus on patients, other customers, and markets), both in the present and in the future, shows that health care administrators and professionals do not fully appreciate the importance of addressing health care customer and market requirements. It is obvious that health care administrators and professionals are still uncomfortable focusing on customers and markets. The results for performance measures in Category 3 are in sync with the traditional service model in health care. Health care professionals have been accustomed to a service model where the customer has been narrowly defined to include patients and their families, or even more narrowly defined as including only the patients. In this old service model the customers have been seen as "recipients" of care rather than as active participants in the process of care. In the new marketplace, such a service model is not only unsuitable, but also inappropriate if the health care institutions want to re-focus on quality and safety of care, providing patient-centered services, and building a strong business case for patient safety. Similar to borrowing performance measurement approaches from other industries (e.g., aviation, automotive industry, etc.), borrowing customer and market approaches from other industries (e.g., from other service industries) may prove beneficial for focusing health care institutions' attention on better serving their customers and expanding their market share.

The outcomes of this study suggest that to implement, maintain, and improve patient safety systems, health care administrators should do the following:

- Effectively communicate the priority of patient safety to all stakeholders, actively seeking feedback on patient safety and using the information for patient safety improvements.
- Ensure ethical communication with stakeholders in regard to patient safety and utilize ongoing monitoring and analysis of patient safety outcomes for patient safety improvement.
- Incorporate national databank data and clinical practice guidelines as patient safety performance benchmarks in institution's strategic plan and monitor staff performance against the adopted benchmarks.
- Develop, monitor, regularly review, and improve institution's patient safety action plans.
- Plan, coordinate, and align institutional patient safety activities to ensure patient safety education of institution's leadership, medical

staff, and patients at the individual, team, departmental, and institutional levels, as appropriate.

- Design and implement comprehensive, accessible, and user-friendly systems for recording, monitoring, tracking, and analyzing adverse events and near miss reporting from both staff and patients, and use the results of the analysis for further patient safety improvement.
- Plan, align, and monitor institution-wide processes for facilitation of information transfer and communications through clinical information technology.
- Integrate institution's patient safety goals into everyday health care delivery functions and protocols, regularly review and improve the health care delivery protocols, and continuously monitor and evaluate institution's performance toward its safety goals.
- Adopt clinical protocols for administration of high-alert medications.
- Coordinate departmental and interdepartmental patient safety infrastructures to reduce variability in health care delivery and to improve performance.
- Design and implement an institutional mechanism for continuous monitoring, improvement, and sustainability of patient safety outcomes in health care delivery.

The experts on the Delphi panel emphasized the importance of the “non-punitive” aspect of medical error reporting systems based on the specific message that health care professionals should not feel threatened when reporting medical errors or near misses. Designing and utilizing nonpunitive and reliable reporting systems that allow confidential or anonymous reporting of adverse events and near misses is essential if health care institutions are to become learning organizations and if they are to use medical error and near miss data for improvement of their patient safety systems.

## **Discussion**

The Institute of Medicine (IOM) has recognized the underdevelopment of patient safety systems in most U.S. health care settings and has rigorously emphasized the need for implementation of comprehensive patient safety systems as an integral part of all health care organizations.<sup>17</sup> Patient safety systems, which are multi-level and multifaceted, include a culture of safety and strong organizational support for implementation and improvement.

Physician clinical performance measures intend to measure individual physician's clinical practice behavior and adherence to evidence-based, objective clinical practice criteria. Thus, such an assessment is based on the availability of clinical evidence that certain processes and behaviors can be linked to patient outcomes. Such evidence is limited for the majority of clinical specialties.<sup>18</sup>

Therefore, it is very difficult to formulate robust clinical performance measures, and considerable variation will continue to exist between clinical specialties and facilities. In order to expand the relationship between its accreditation criteria and the MBNQA framework, as well as to ensure compatibility with the principles of quality management, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) re-modeled its accreditation process and introduced *Tracer Methodology* (part of the *Shared Visions – New Pathways* accreditation process), which is focused on processes critical to patient safety.<sup>19, 20</sup>

Traditionally, efforts toward improvement in medicine have more often than not targeted individuals and centered on training, rules, and sanctions rather than on systems and system failures.<sup>21–25</sup> However, medical errors occur as the result of a chain of errors within a faulty system that is not designed to detect errors and intercept them. Thus, while individual responsibility for deviating from policies and procedures remains important, errors can be eliminated only through focusing beyond the individual and focusing on systems design changes supported by top-level management.<sup>17, 24, 26–29</sup>

Patient safety and quality definitions continue to be the focus of expert debates. For the last several years the Agency for Healthcare Research and Quality (AHRQ) has sponsored patient safety research to identify patient safety risks, design patient safety practices, educate health care professionals, and monitor patient safety trends. It also has started initiatives to identify best clinical practices and train patient safety researchers. Other agencies, such as the Centers for Disease Control and Prevention, Food and Drug Administration, and Veterans Administration, have supported patient safety research and patient safety activities as well as legislative efforts focused on creating voluntary medical-errors reporting systems. Despite these efforts, patient safety improvements will not be achieved without standardizing patient safety definitions, terminology, measurements, and databases.<sup>17, 30</sup> Essential steps include utilizing quality improvement tools, recognizing the systemic roots of medical errors, performing failure mode and effects analysis (FMEA), designing fail-safe systems, and training medical professionals in error reduction team processes.<sup>17, 25, 29, 31–36</sup>

Patient safety is a subset of health care quality.<sup>30</sup> Therefore, successful quality improvement programs should start with setting the scene (i.e., institution-wide policies and procedures for deploying systems for clinical performance assessment as well as recognizing, analyzing, and dealing with the systems nature of medical errors).<sup>18, 25</sup> Health care processes are interdepartmental in nature and should be designed and assessed by cross-functional teams, including clinical, administrative, and other staff members. Thus, linking patient information systems to administrative and financial information systems appears critical for measuring health care outcomes.<sup>17, 19</sup> The role of leadership in using process data for improvement rather than for disciplinary actions is extremely important in the patient safety improvement effort. Performance data collection should be based on accepted performance guidelines sets, such as accreditation standards or the Baldrige Healthcare Criteria for Performance Excellence.

Health care futurists have put the issues of patient safety and quality improvement, along with the issues of implementation of clinical information systems, e-health, and electronic medical records, among the top trends in U.S. health care.<sup>37</sup> The problem in health care is not the lack of tools to improve patient safety, but rather the low priority traditionally assigned to this goal.<sup>38</sup> While quality experts agree that the cause for the majority of performance problems is the health care delivery system itself, and accident investigators agree that most disasters in complex organizations have long incubation periods and manifest with multiple discrete “small” events over a long period of time, the study of human error in medicine is a relatively new field that is trying to establish its boundaries, terminology, and taxonomy. Additionally, the current focus of attention is still predominantly on individual performance and responsibility. Since health care organizations usually create department or service-specific measures and reports, data are collected and reported separately, and no particular individual or department has comprehensive information on the whole organizational picture.<sup>39</sup>

Reason<sup>40</sup> developed a model for organizational accidents in complex industrial systems that considered not only the actions of the individuals involved, but also the conditions in which the tasks were performed and the organizational context in which the incident occurred. He distinguished between *active* failures as unsafe acts of omission or commission and *latent* failures stemming from managerial decisions, process organization, and system design. Thus, latent failures provide the work conditions where unsafe acts occur. Such conditions include inadequate knowledge, training or expertise, heavy workloads, inadequate supervision, inadequate systems of communication, inadequate maintenance of plant and equipment, and stressful environment.<sup>40</sup> The accident opportunity has to penetrate through several layers of defense systems on managerial, psychological, environmental, and local levels before an opportunity window (also called “the Swiss cheese model”) allows the error to reach a patient.<sup>40, 41</sup> Thus, discipline should be not the first, but rather the last action taken against staff members as a result of reported errors.<sup>42</sup> Focusing on systems analysis, education, development, and dissemination of clinical practice guidelines; using automated “fail-safe” systems; and utilizing computer reminders have been identified as prevention factors for adverse events in health care. Studying these factors and their interrelations has been recommended for prevention of medical errors.<sup>43</sup> Patient safety, as a property of the health care systems, can be created or broken in systems, and correcting systems’ vulnerabilities is the efficient way to go.<sup>44</sup>

Successful health care leaders for the 21<sup>st</sup> century are expected to build the capacity of the health care system for improvement. Chief executive officers in health care organizations should be able to recognize the importance of aligning all organizational strategies for improvement—operations, professional development, and financing—and systematically approach organizational and personal improvement through performing patient assessment, process assessment, data gathering, and critical assessment of the current literature.<sup>17, 45</sup> It is widely agreed that systems lie at the base of the majority of medical errors and that improvement can be achieved through system re-design and institutional self-

assessment.<sup>17, 30, 34</sup> The responsibility for creating and endorsing such an institution-wide improvement system ultimately resides within the health care executive leadership. A system for patient safety improvement should be based on the principles of simplification, standardization, stratification, improved communication, designing easy “default” procedures, reasonable automation, process mapping, recognition of the limitations of human vigilance, and encouragement of error reporting. As patient safety was declared an issue of major national interest with the series of IOM publications,<sup>17, 46, 47</sup> policymakers, health care professionals, and consumers started recognizing the need to assess, monitor, and improve health care safety.

The interrelationship and interdependence of the MBNQA categories illustrate that it is important for institutions to develop all MBNQA categories. The patient safety tool resulting from this study utilizes systems approach for advancing the MBNQA model in the area of patient safety. Within the MBNQA framework, the study participants identified a hierarchy of categories, both for the present and the future, that will assist health care administrators in selecting the category needing most improvement in their respective institutions. It is important to start with leadership commitment to lead the patient safety process at the institutional level. In the future, measurement and analysis of patient safety data will continue to drive leadership direction, funds allocation, and strategic planning activities. Patient safety problems occur frequently and with significant impact on individual health care facilities and the health care industry as a whole. A strong business case for patient safety and institution-wide support for implementation, management, and improvement of patient safety systems will justify allocation of appropriate funds and required process changes.<sup>17, 27, 30, 46, 47</sup> The MBNQA criteria give a structured matrix for producing results and can be used as an objective tool for building the business case for patient safety. The applicator tool based on the MBNQA criteria provides a venue for health care organizations to study patient safety issues within an organization and to understand which components need to work together to accelerate patient safety outcome improvement.

## **Conclusions**

Patient safety practices are multidimensional and difficult to assess and reach through all organizational levels. Implementation of patient safety systems based on the MBNQA model may ensure that health care institutions provide the systemic approach to quality services they intend to provide. The critical processes and performance measures identified in this research will be useful for health care institutions in designing, implementing, and improving patient safety systems. This study used the MBNQA model, a proven model that has been refined over the past 17 years and that has been adopted nationally by numerous health care organizations to manage and advance improvement strategies in their systems. The approach to patient safety thus far has been reflective primarily of departmental issues, or has been led by narrowly tailored, disease-based priorities and outcomes. According to the current patient safety approach, specific patient outcomes, processes, or activities that have not been measured are not reflected,

analyzed, or taken into consideration for future patient safety initiatives. In light of this, a systems approach, based on the already refined Malcolm Baldrige model, offers the advantage of a more holistic approach to building patient safety systems at the institutional level. The patient safety applicator tool, which extends the Malcolm Baldrige systems model to patient safety, is intended to support senior health care administrators in achieving and sustaining improvement results and may also serve as a means for evaluating existing patient safety initiatives or for guiding the planning of new processes for better health care delivery. Moreover, the identified patient safety applicator tool will assist health care institutions in using the MBNQA Health Care Criteria for Performance Excellence for self-assessment and quality improvement. The three levels of this patient safety applicator tool are intended to meet the needs of health care organizations that are at different stages of their patient safety journey.

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